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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,779	03/08/2001	James E. Hildreth	JHU1710-3	9936

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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	14

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,779	HILDRETH, JAMES E.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-30,33-37 and 40-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 19-30, 33-37, and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8, 12-13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Objections/Rejections Set For the in Office Action dated April 4, 2002

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

2. Claims 3, 20, and 34 are objected to because of the following informalities: Misspelling of the term "herpesvirus".

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron).

Response to Amendment

5. In the amendment filed July 18, 2002, the specification was amended. Claims 16-18, 31, 32, 38, and 39 were canceled. Claims 1, 3, 4, 9, 13, 14, 20, 23, 28, 29, 34, 37, and 40 were amended. Claims 46-51 were added. An action on the merits of claims 1-15, 19-30, 33-37, and 40-51 is contained herein below.

6. In regards to Priority under 35 U.S.C. § 119, applicant's amendments filed July 18, 2002 have been fully considered and the requirements for obtaining benefit of priority have been met.

7. In regards to Objections to the claims, applicant's amendments filed July 18, 2002 have been fully considered and have overcome the objections set forth by the examiner in the Office Action dated April 4, 2002.

8. In regard to Rejections under 35 U.S.C § 112, second paragraph, applicant's amendments filed July 18, 2002 have been fully considered and have overcome the rejections set forth by examiner in the Office Action dated April 4, 2002 (claim canceled).

9. Rejections under 35 U.S.C § 103(a), applicant's amendments filed July 18, 2002 have been fully considered. Rejections are withdrawn due to the citation of new art. Previously rejected and newly added claims are addressed in a new rejection below.

Response to Arguments

10. In regard to Rejections under 35 U.S.C § 103(a), applicant's arguments have been considered but they are not persuasive. Pending claims have been amended to read upon methods and compositions "consisting essentially of β-cyclodextrin". In regards to the new claim language, for the purposes of applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See MPEP 2111.03. No such indication is given in the

specification. The specification describes compositions "comprising" a b-cyclodextrin (page 3, lines 28-32; pages 4-5).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-15, 19-30, 33-37, and 40-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-15, 19-20, 22-30, 33-37, and 40-45 of copending Application No. 09/801,393 ('393). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding claims 1-4, 6-15, 19-20, 22-30, 33-34, and 36, the instantly disclosed invention differs from '393 (claims **1-4, 6-15, 19-20, 22-30, 33-34,** and **36**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin. However, the instant disclosure teaches that composition of the method

generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32).

Regarding claim 5, the instantly disclosed invention differs from '393 (claim **3**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin and is not limited to a method wherein the virus is *Herpes simplex* virus. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* (page 3, lines 16-20).

Regarding claim 21, the instantly disclosed invention differs from '393 (claim **20**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin and is not limited to a method wherein the virus is *Herpes simplex* virus or HIV. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* or HIV (page 3, lines 16-20).

Regarding claim 35, the instantly disclosed invention differs from '393 (claim **35**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin and is limited to a method wherein the virus is HIV. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* or HIV (page 3, lines 16-20).

Regarding claim 37 and 46-49, the instantly disclosed invention differs from '393 (claim **37**) in that '393 is drawn to a composition comprising about 30 mM or less of a β-cyclodextrin and an agent. However, the composition of '393 consists essentially of a β-cyclodextrin, as the agent is not required for treating a sexually transmitted disease but may be optionally included (see page 25-27 of '393). '393 further discloses that the β-cyclodextrin can be formulated in any pharmaceutically acceptable carrier, provided that the carrier does not affect the activity of the β-cyclodextrin in an undesirable manner. Thus, the composition can be, for example in the form of a cream, a foam, a jelly, a lotion, an ointment, a solution, a spray, or a gel (page 25, lines 30-32 and page 26, lines 1-15). '393 further teaches that the amount of cyclodextrin used in the composition is about 1 to 100 mM, generally about 5 to 30 mM (page 28, lines 5-20).

Regarding claims 40-41 and 43-45, the instantly disclosed invention differs from '393 (claims **40-41** and **43-45**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. However, the instant disclosure teaches that composition comprises about 0.1% to 3% of a β-cyclodextrin as the active agent (page 29, lines 2-9).

Regarding claim 42, the instantly disclosed invention differs from '393 (claim **42**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. '393 does not disclose the composition being a vaginal disk. However, the instant disclosure teaches that composition comprises about 0.1% to 3% of a β-cyclodextrin as the active agent (page 29, lines 2-9) and '393 teaches that the

composition as being in a form suitable for topical administration to a subject, particularly intravaginal [vaginal disk] (page 25, lines 15-29)

Regarding claims 50-51, the instantly disclosed invention differs from '393 (claim **40**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. However, the instant disclosure teaches that composition comprises about 0.1% to 3% [0.1 to 2 grams, generally 0.25 to 0.75 grams] of a β-cyclodextrin as the active agent (page 29, lines 1-9).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1-15, 19-30, 33-37, and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in view of Baert et al. WO 97/18839 (Baert) and Sokal et al. US 5,819,742 (Sokal).

Claims 1-15, 19-30, 33-37, and 40-49 are directed to compositions consisting essentially of a β-cyclodextrin and methods of using such compositions to reduce the risk of transmission of a sexually transmitted disease.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug

and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that: 1) Bergeron does not limit its disclosure to β-cyclodextrins, but is drawn to cyclodextrins in general. Bergeron does not disclose the use of a 2-hydroxypropyl –β-cyclodextrin; 2) Bergeron does not teach the amounts of cyclodextrin used (teaching is silent on amounts used) 3) Bergeron does not teach the composition being formulated into a suppository, film, condom, suppository, bioadhesive polymer, diaphragm, absorptive substrate, glove, sponge, or tampon. However, these deficiencies would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert and Sokal.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert includes loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Baert further teaches the ratio of active ingredient to cyclodextin varies widely and that ratios of 1/100 [essentially cyclodextrin] to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

Sokal teaches a vaginal device (tampon) for providing physical and chemical barriers for protection against the sexually transmitted diseases (column 1, lines 56-58).

The device is a towelette formed of an absorbent sheet material and a flowable preventive formulation incorporated into the towelette by absorption (column 1, lines 58-63). The preventive formulation may include one or more pharmacologically active agents (column 1, lines 59-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the amounts claimed by applicant since β-cyclodextrins in these amounts (including 2-hydroxypropyl-β-cyclodextrin) are taught by Baert for pharmaceutical compositions which are useful for treating HIV-infected patients. It would have also been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition disclosed by Bergeron into a film, glove, or condom since Bergeron teaches inclusion of a film-forming component in the formulations. Based on these teachings it obvious to formulate the compositions of Bergeron into a film. It would have been equally obvious to further formulate the film into a glove or condom since gloves ("rubber gloves") and condoms are basically films and are well known in the art for the prevention of sexually transmitted diseases. It would have also been obvious to incorporate the composition into a tampon or sponge since Sokal teaches vaginal devices incorporating pharmacological agents for the prevention of the transmission of sexually transmitted diseases. One would have been motivated to do what applicant claims in order to provide an effective formulation for preventing sexually transmitted diseases in an already known and widely used form.

Conclusion

16. Claims 1-15, 19-30, 33-37, and 40-51 are pending. Claims 1-15, 19-30, 33-37, and 40-51 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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October 21, 2002